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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/506,803

01/14/2005

Robert Langc

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06/14/2006

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EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT

PAPER NUMBER

3733

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/506,803	<b>Applicant(s)</b> LANGE, ROBERT ✓	
	<b>Examiner</b> Jerry Cumberlandge	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>09/07/2004</u> . | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Specification***

The disclosure is objected to because of the following informalities:

On page 2, lines 5-7, the sentence beginning with "The plate can be squeezed..." is not a complete sentence.

On page 2, line 13, there are two periods at the end of the sentence and the word "artefact" should be changed to the word --artifacts--.

On page 3, line 14, there is no space between "10" and the word "and".

On page 4, lines 2-3, a comma is needed between "1" and "rods".

On page 4, line 6, the word "a" is not needed.

On page 5, lines 15-16, the word "sacrificed" should be changed to the word --sacrificed--.

On page 5, line 22, no period is needed after the number 14.

On page 5, line 25, the word --an-- is needed before the word "axial".

On page 6, line 2, the word "sacrifying" should be changed to the word --sacrificing--.

Appropriate correction is required.

### ***Claim Objections***

Claim 1 is objected to because of the following informalities: The word --A-- should be inserted before the word "Longitudinal" and the word --a-- should be inserted before the word "connecting". Appropriate correction is required.

Claim 1 is objected to because of the following informalities: The word "that" should be changed to the word --said--. Appropriate correction is required.

Claims 2-11 are objected to because of the following informalities: The phrase --A longitudinal implant and a—should be inserted before the word "Connecting". Appropriate correction is required.

Claims 5 and 12 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims 5 and 12 have not been further treated on the merits.

Claim 7 is objected to because of the following informalities: The word "comprising" should be changed to the word --comprises--. Appropriate correction is required.

Claim 7 is objected to because of the following informalities: The word --an—should be inserted before the word "exteriorly". Appropriate correction is required.

Claim 10 is objected to because of the following informalities: The word "comprising" should be changed to the word --comprises--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claims 1-12 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 1, lines 1-3, applicant positively recites part of a human, i.e. "...wherein said longitudinal implant is fastened to bones on either side of a damaged area through that connecting device...". Thus claims 1-12 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

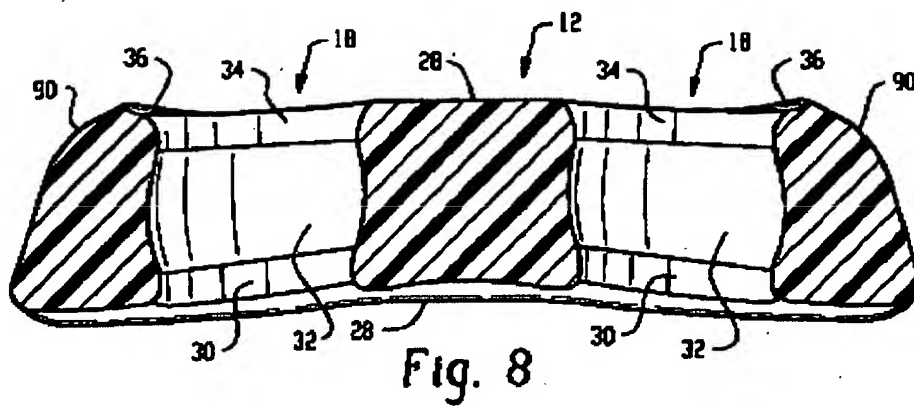
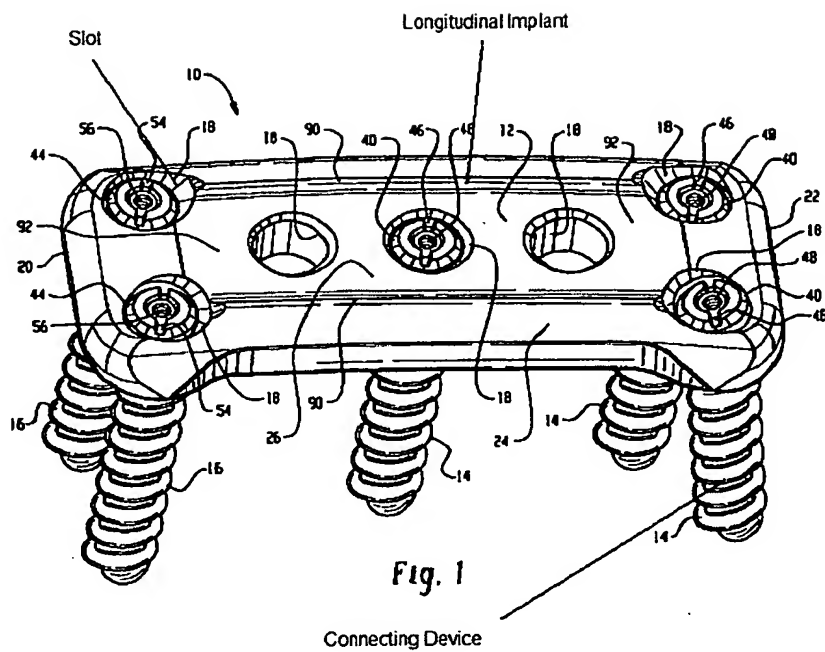
A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 9, 11, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Eisermann et al. (US Pat. 6342055 B1). Eisermann et al. disclose

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a longitudinal implant and connecting device (Fig. 1 below). The implant is comprised of a filament or fiber composite material (column 5, lines 6-10) and the connecting device is made of a material harder than the implant (column 3, lines 13-16). The longitudinal implant is made of a carbon filament composite material (column 5, lines 6-10). The filaments are encapsulated in PEEK or PEKEKK (column 5, lines 6-10). The filaments are oriented (column 5, lines 10-15). The implant is an elongated plate having a longitudinal slot extending along a substantial portion of its length (Fig. 1). The implant is a rail. According to The American Heritage Dictionary of the English Language: Fourth Edition a rail is "a bar extending horizontally between supports, as in a fence." The implant disclosed is a bar that extends between supports, the supports being the pedicle screws (Fig. 1). It has a rectangular cross section (Fig. 8). The filaments are woven. The definition of woven according to The American Heritage® Dictionary of the English Language: Fourth Edition is "made by weaving" and the definition of weave from the same source is "to construct by interlacing or interweaving strips or strands of material." The fibers are randomly oriented, so the fibers are overlapping each other at various points, and are interlaced and interwoven.



**Claim Rejections - 35 USC § 103**

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eisermann et al. (US Pat. 6,342,055 B1) in view of Morrison et al. (US Pat. 6,280,445 B1). Eisermann et al. disclose the claimed invention except for the pedicle screw having an upper section having a width greater than the width of the slot and an exteriorly threaded portion extending outwardly from the section and extending through the slot, an interiorly threaded nut, and the screw and the nut being made out of titanium. Morrison et al. disclose a pedicle screw having an upper section having a width greater than the width of the of the slot (Figs. 3 and 11d below) and an exteriorly threaded portion extending outwardly from the section and extending through the slot (Fig. 3), an interiorly threaded nut (Fig. 13c below), and the screw and nut being made out of titanium (Morrison et al., column 12, lines 42--44). The pedicle screw having an upper section having a width greater than the width of the slot and an exteriorly threaded portion extending outwardly from the section and extending through the slot disclosed by Morrison et al. has such a configuration as to allow the screw top to protrude through the slot and allow a threaded nut to be placed over the screw top to attach the screw to the plate (Morrison et al., column 10, lines 38-52 and column 11, lines 33-35). The nut and the screw are made out of titanium,

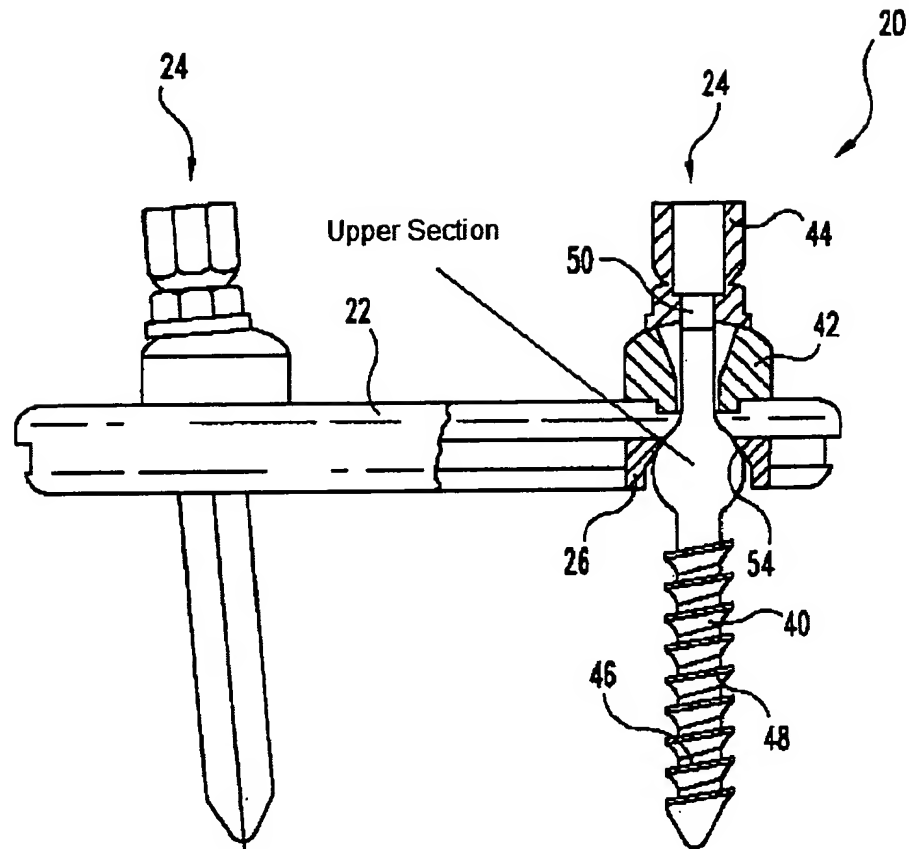


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due to the sturdiness and biocompatibility of that material (Morrison et al., column 12, lines 42-44). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to construct the assembly of Eisermann et al. with the upper section of the pedicle screw having a width greater than the width of the of the slot and an exteriorly threaded portion extending outwardly from the section and extending through the slot, an interiorly threaded nut, and the screw and nut being made out of titanium in view of Morrison et al., in order for the plate to be gripped by the pedicle screw assembly (the bone connector) and to gain the benefit of the biocompatibility and

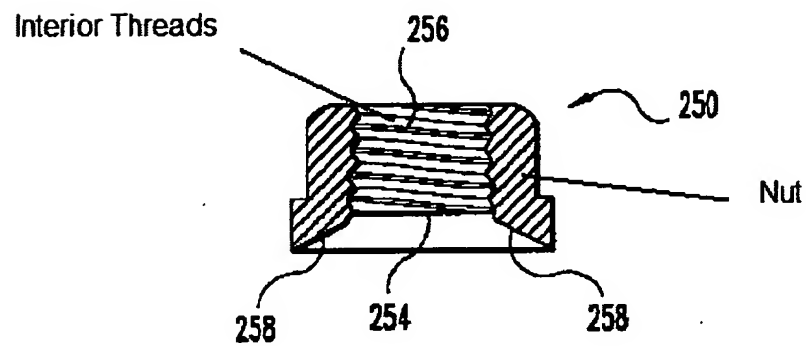
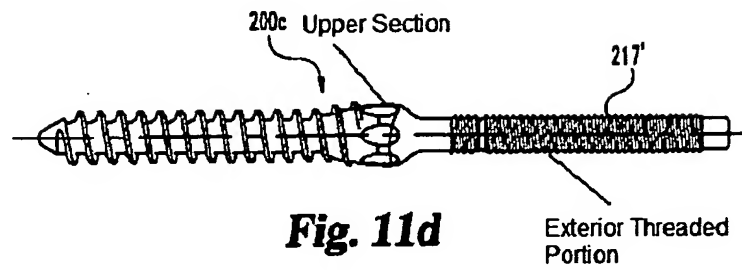
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sturdiness of titanium.



**Fig. 3**

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**Fig. 13c**

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being over Small et al. (EP 0637437 A) cited in IDS filed on 09/07/2004.

Small et al. disclose a longitudinal implant and connecting device (Fig. 1). The implant is comprised of a filament or fiber composite material (page 3, lines 36-38). The longitudinal implant is made of a carbon filament composite material (page 3, lines 36-38). The filaments are encapsulated in PEEK or PEKEKK (page 3, lines 36-38). The filaments are oriented (page 4, lines 19-20). The implant is an elongated plate having a longitudinal slot extending along a substantial portion of its length (Fig. 1). The connecting device comprises a pedicle screw having an upper section having a width greater than the width of the slot and an exteriorly threaded portion extending outwardly from the slot and an exteriorly threaded portion extending outwardly from the section and extending through the slot (Fig. 1). The connecting device comprises an interiorly threaded nut (Fig. 1). The implant is a rail (Fig. 1). It has a rectangular cross section (Fig. 1). The filaments are woven.

Small et al. disclose the claimed invention except for the screw and nut being constructed of titanium. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the screw and nut of Small et al. of titanium, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See attached form PTO-892.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



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